





697 Waverly Street, Framingham, MA 01702
Toll Free: 800.994.6322 Fax: 508.820.1616

www.neccrx.com



697 Waverly Street, Framingham, MA 01702

Tel: 800.994.6322 or 508.820.0606

Fax: 888.820.0583 or 508.820.1616

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General Overview of Policies & Procedures for Compounding Sterile Products

NECC operates in accordance with the following general guidelines when compounding sterile products:

A. Facility/Equipment

- a. ISO-5 & ISO-6 Cleanroom(s).
- b. Class 10 Microenvironments (barrier isolator).
- c. Certified by Massachusetts Board of Pharmacy as a pharmacy with a central venous admixture service (CIVAS) in accordance with Board regulations, 247 CMR 6.01 (6)(c).

B. Monitoring & Maintenance

Comprehensive environmental monitoring program

- a. All cleanroom space, air, surfaces and hoods are sampled on a weekly basis, exceeding USP 797.

C. Personnel

- a. All sterile compounding is performed by properly trained and validated registered pharmacists.
- b. Pharmacy personnel are trained/validated by an outside agency, Professional Compounding Centers of America (PCCA).
- c. Personnel are validated on a quarterly basis.

D. Quality Assurance/Quality Control

- a. USP Chemicals are obtained only from FDA registered facilities.
- b. Formulations are sterilized by 0.22 micron filtration or by autoclaving.
- c. Samples from final product batch lots are sent to an independent FDA registered analytical lab for sterility, endotoxin (pyrogenicity) and potency testing.
- d. Tested medication is quarantined and dispensed only after the sample has tested negative for endotoxin and microbial contamination.

- e. The Quality Assurance Team (QAT), made up of employees from all departments within NECC, meets regularly to review all quality related items.
- f. NECC maintains strict environmental testing protocols. Results of these tests are reported via Quarterly QA Reports.
- g. All sterile compounding actions are performed in compliance with NECC's Standard Operating Procedures (SOPs). These SOPs have been "mapped" against USP 797 "Pharmaceutical Compounding – sterile preparations" to ensure that all USP 797 requirements are observed.

E. Use-by Dating

Each dosage form is labeled with a BUD/expiration date appropriate to the formulation obtained from:

- a. Current literature.
- b. Independent stability assay.

F. Packaging

- a. Compounded preparations are packaged in containers meeting USP standards.
- b. Container used depends on the physical and chemical properties of the compounded preparation.

G. Dispensing

There must be a specific practitioner-patient-pharmacist relationship in place to dispense to an individual patient or facility.

H. Shipping

Medications are shipped overnight (usually via FedEx) in an appropriate container to ensure controlled temperatures and product integrity.

I. Licensing

NECC has undertaken a rigorous licensure process thus giving us the ability to legally dispense prescription medication in all 50 states.



Company Overview

NECC (New England Compounding Center) is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients and prescribers. NECC is USP Chapter 797 compliant. Pharmacists formulate all medications with only the highest grade chemicals in the state-of-the-art compounding facility.

NECC Allows you to Order Medication not Available from a Pharmaceutical Manufacturer Due to:

- Discontinuation of Commercial Medication
- Prolonged Back Order
- Product not available in Dosage Form, Strength or Content Needed for Patient

Why NECC?

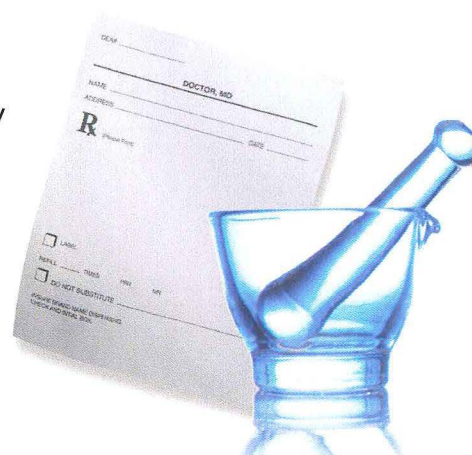
- Wide Range of Compounded Preparations
- Reliable Extended Beyond Use Dating
- Customization to meet your Patient's or Facility's needs
- Bar Coding
- Quarterly QA Reporting

Equipment and Facility

- State-of-the-Art Nationally Licensed Compounding Facility
- Class-1,000 (ISO-6) Cleanrooms
- Class-10 (ISO-4) Isolation Chambers / Glove Boxes

Personnel

- Highly Specialized and Extensively Trained Compounding Pharmacists and Certified Technicians
- Experienced Formulation Research and Development Team



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COMMITMENT TO QUALITY

All Formulations are:

- USP 797 Compliant
- Strictly Enforced Environmental Monitoring Program
- Comprehensive End-Product Testing Program
(Independent Analytical Laboratory Used for ALL End-Product Testing)
 - Sterility Testing
 - Endotoxin Testing
 - Quantitative Testing
 - Extended Stability Testing



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DOJ_NECC001558193

Account Information/ Credit Application

Shipping Address:

Facility Name: _____

Street: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____ Email: _____

Shipping Contact Name: _____

Billing Address:

Facility Name: _____

Street: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____ Email: _____

Accounts Payable Contact Name: _____

ARE PURCHASE ORDERS REQUIRED? Yes _____ No _____ PO# _____

DO YOU PAY BY CREDIT CARD? Yes _____ No _____

Type _____ Number _____ Exp Date _____

Bank Reference:

Bank Name: _____ Contact Name: _____ Phone: _____

Bank Account #: _____ Type: _____

Bank Address, City, State, Zip: _____

Trade Reference:

Company Name	Contact Address	City	State	Zip	Phone
--------------	-----------------	------	-------	-----	-------

1. _____					
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The signature below represents and warrants that the party signing below is an authorized representative of the company and that the information provided herein is a complete and accurate representation of the company's financial situation as of the date hereof and that the party authorizes trade and bank references to release any information necessary to assist in establishing a line of credit.

Name: _____ Title: _____

Signature: _____ Date: _____

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Prescription Order Form

697 Waverly Street, Framingham MA 01702
800.994.6322, 508.820.0606.
FAX 888.820.0583 or 508.820.1616

DATE: _____

NAME OF FACILITY: _____ PHONE NUMBER: _____

ADDRESS: _____ CONTACT NAME: _____ P.O. #: _____

We **must** have Facility name & address to process your prescription order – *Thank you.*

Name of Patient	Name of medication to be compounded	Strength (%, mg/ml, u/ml)	If <i>preservative-free</i> , write in p/f	Unit size (mL, gm...)	# of units	Directions

Physician's Name/Signature: _____ DEA Number: _____

For NECC Use Only

Verification: Institutional Agent: _____ NECC Agent: _____ Date: _____ Time: _____

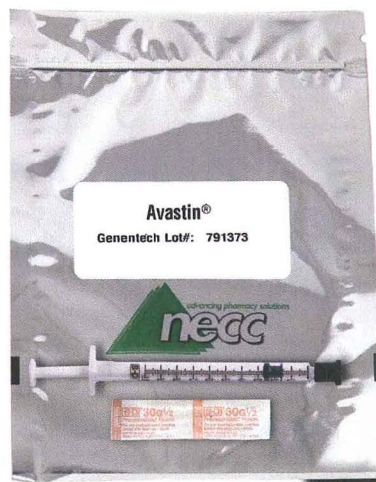
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DOJ_NECC001558195

Unit-Dose Repackaged Avastin™

(Aseptic Repackaging Service Provided by NECC)

- Repackaged Avastin™ (PF) 25mg/mL
- Dispensed in a 1cc Syringe with enough Overfill for a 0.05mL Deliverable Dose
- Supplied with a Separate, New & Sterile 30g 1/2" Needle
- Packaged in Tamper Evident and Light Resistant Mylar Bags
- Cold Shipped



NECC (New England Compounding Center) is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients and prescribers. NECC is USP Chapter 797 compliant. Pharmacists formulate all medications with only the highest grade chemicals in the state-of-the-art compounding facility.

Please call today to discuss your patient's prescription needs.

Ken Boneau, MBA
Regional Sales Manager

Direct Line: 508.656.2667
Toll Free: 888.777.9730 ext. 667
Cell: 774.286.6059
Fax: 508.820.9401
Email: kboneau@medicalsalesmgmt.com

Exclusive Sales Representative:
Medical Sales Management, Inc.
771 Waverly Street, Framingham, MA 01701
DOJ_NECC001558196x.com

Dilation Drops

(Concentrated & Preservative-Free)

Is Dilating Your Patient's Eyes Driving Your Staff to Tears?

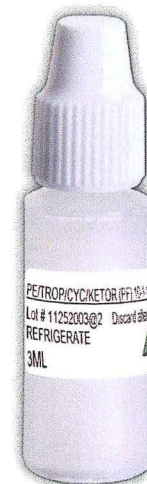
Four Popular Examples:

Combination 1	Combination 2	Combination 3	Combination 4
Tropicamide 1%	Tropicamide 1%	Tropicamide 1%	Tropicamide 1%
Cyclopentolate 1%	Cyclopentolate 1%	Cyclopentolate 1%	Cyclopentolate 1%
Phenylephrine 2.5%	Phenylephrine 10%	Phenylephrine 2.5%	Phenylephrine 10%
		Ketorolac 0.5%	Ketorolac 0.5%

Many regimens used to prepare a patient for cataract surgery require nurses to administer as many as 6 individual ophthalmic medications! NECC can help by compounding these agents into concentrated combinations that will greatly reduce the number of doses required to prepare the patient.

All CSP Formulations are:

- Compounded for your patients by pharmacists
extensively trained in aseptic compounding
- Prepared in a Class 10 Microenvironment (barrier isolator)
- Comprised of USP quality ingredients



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Attn: Pharmacy Buyers

NECC can Provide you with Currently Backordered Items

1. **Etomidate** 2 mg/mL, 10 mL Fill Volume in a 10 mL Amber Vial
2. **Metoclopramide** Injection 5mg/mL, in a 3mL Syringe
3. **Acetylcysteine** 10 & 20% Oral / Inhalation Solution (pf), 2mL or 4mL in a 5mL Syringe
4. **Ketorolac** 30mg/mL (pf), in a 3mL Syringe
5. **Potassium Chloride** 2mEq/mL (pf), in Various Vial Sizes
6. **Nalbuphine** 10mg/mL & 20mg/mL (pf), 1mL in a 2mL Vial
7. **Dipyridamole** 5mg/mL in a 10mL Vial
8. **Furosemide** 10mg/mL, 2mL in a 2mL Amber Vial, 4mL in a 5mL Amber Vial & 10mL in a 10mL Amber Vial
9. **Prochlorperazine** 5mg/mL, in a 2mL Vial
10. **Atropine** .4mg/mL & 1mg/mL (pf), in Various Vial or Syringe Sizes
11. **Potassium Acetate** Injection
12. **Potassium Phosphate** Injection
13. **Sodium Phosphate** Injection
14. **Mannitol** 20% (pf), in Various Vial or Syringe Sizes
15. **Naloxone** 0.4mg/mL & 1mg/mL (pf)
16. **Sodium Acetate** Injection
17. **Lidocaine** 1%, 2% & 4% Injection (p) or (pf), in Various Vial or Syringe Sizes
18. **Bupivacaine** 0.25% & 0.50% (p) or (pf), in Various Vial or Syringe Sizes
19. **Mitomycin** Sterile Solution for Ophthalmic Use 0.2- 0.5mg/mL (Concentration can be Customized), in a 3mL Syringe
20. **Adenosine** 3mg/mL (pf), in Various Sizes
21. **Caffeine Citrate** 20mg/mL Injectable and Oral, in a 3mL Vial or Syringe
22. **Lidocaine** 5% in Dextrose 7.5% (pf), in Various Vial Sizes
23. **Promethazine** 25mg/mL or 50mg/mL (p) or (pf), in Various Vial or Syringe Sizes
24. **Sodium Bicarbonate** 4.2% & 8.4% (pf), in Various Vial Sizes



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OPHTHALMOLOGY CUSTOM MEDICATIONS

“Pre-Cataract” Dilation Drops (Preservative-Free)

(PE) Phenylephrine
(T) Tropicamide
(C) Cyclopentolate
(K) Ketorolac

- | | |
|--------------|-----------------|
| #1) PE-T-C | 2.5%-1%-1% |
| #2) PE-T-C | 10%-1%-1% |
| #3) PE-T-C-K | 2.5%-1%-1%-0.5% |
| #4) PE-T-C-K | 10%-1%-1%-0.5% |

Avastin™ - “Unit-Dose Syringe”

1.25mg/0.05mL
Syringe/ Needle/ Tamper-Evident,
Light-Resistant Mylar Bag

Triamcinolone Acetonide

40mg/mL (PF), 1mL Vial

Frozen/Unit-Dose Antibiotics

Vancomycin 10mg/mL, 1mL Vial
Ceftazidime 22.5mg/mL, 1mL Vial

Hyaluronidase

150u/mL, 1mL or 10mL Vial

Mitomycin

0.2-0.5mg/mL, 1mL Volume in a
3mL Syringe, “Frozen” Unit of Use

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DOJ_NECC001558199

Attn: Ophthalmologists

Many Ophthalmologists are finding it difficult to obtain the medications they need because the required formulations are not commercially available in the desired concentrations and/or dosage forms.

NECC can help by providing compounded medications on a patient-specific basis. Are you having trouble finding...?

- Betadine® (Povidone Iodine 5%-15%, Unit Dose Syringe/Dropper)
- EDTA Preservative-Free (1%-15%)
- Ophthalgan® (Sterile Glycerin)
- Hyaluronidase
- Dilation Drops (Concentrated Combinations)
- Osmoglyn®
- Avastin™ (Unit Dose Syringe)
- Mitomycin (Frozen/Unit Dose)
 - Available in Various Concentrations

Please call today to discuss your patient's prescription needs.



advancing pharmacy solutions
necc

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Unit-Dose Repackaged Avastin™

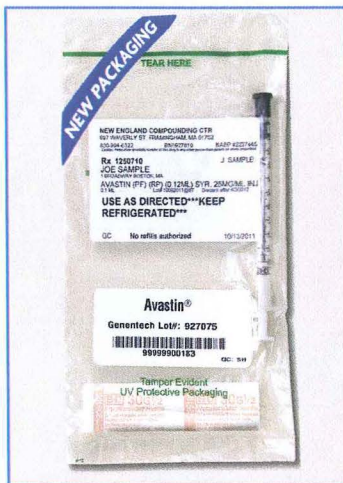
(Aseptic Repackaging Service Provided by NECC)

NECC- 2 Piece System

vs.

Other - 1 Piece System

- 1) Avastin™ syringes are filled in a Class-10 Isolation Chamber/Glove Box, inside a Class-1000 cleanroom. The pharmacist is completely isolated from the filling process.



* Product is aseptically filled via "Syringe to Syringe" "Closed" aseptic process.

- 2) A Two Piece System (1 Sterile Capped Syringe & 1 Unused Commercially Packaged Sterile 30g Needle) is provided.

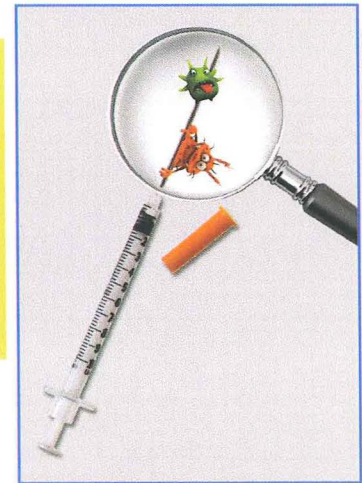
- 3) NECC tests the sterility of "Every" lot dispensed.

- 1) Hundreds of doses are individually drawn into insulin syringes from a "single-dose" vial thru a rubber stopper. This needle will eventually be injected into your patient's eye.

* This process removes the sterile lubricant from the needle's surface and increases the possibility of the contamination of this needle with rubber particles from the stopper and plastic particles when reapplying the plastic syringe cap.

- 2) A One Piece System (1 Re-capped Insulin Syringe with a "Used" Non-Sterile Needle) is provided.

- 3) Do "They" test at all?



- Repackaged Avastin™ (PF) 25mg/mL
- Dispensed in a 1cc Syringe with enough Overfill for a 0.05mL Deliverable Dose
- Supplied with a Separate, New & Sterile 30g 1/2" Needle
- Packaged in Tamper Evident and UV Protective Bags
- Cold Shipped



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Trouble Finding Preservative-Free Kenalog®?

NECC Provides a Compounded Formulation of Preservative-Free Triamcinolone Acetonide

- Available in 40mg/mL
- Provided in a 1mL & 5mL Amber Vial
- Beyond Use Date: 6 Months
- Storage: Room Temperature



All CSP Formulations are:

- USP 797 Compliant
- Compounded for your patients by pharmacists extensively trained in aseptic compounding
- Prepared in a Class 10 Microenvironment (barrier isolator)
- Comprised of USP quality ingredients

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Hyaluronidase

- 150u/mL
- Provided in a 1mL or 10mL Sterile Vial
- Beyond Use Date: 180 Days
- Storage: Refrigerated



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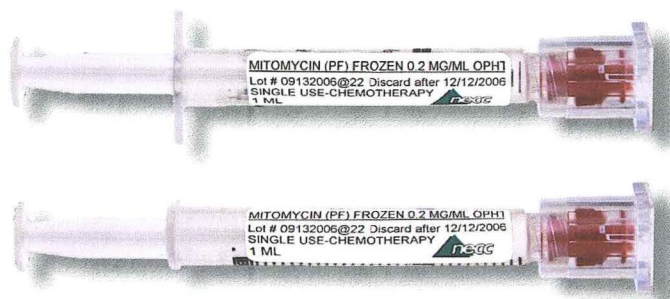
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Mitomycin

(For Ophthalmic Use)

- Sterile Solution Available in 0.2 - 0.5mg/mL or Customized Concentrations
- 1mL Volume Dispensed in a 3mL Syringe
- Beyond Use Date: 3 Months
- Storage: Frozen



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Do You Miss Rev-Eyes®?

NECC Provides a Compounded Formulation of Dapiprazole

- 0.5% Drop, Preserved
- Provided in a 3mL Dropper
- Already Reconstituted
- Beyond Use Date: 120 Days
- Storage: Room Temperature



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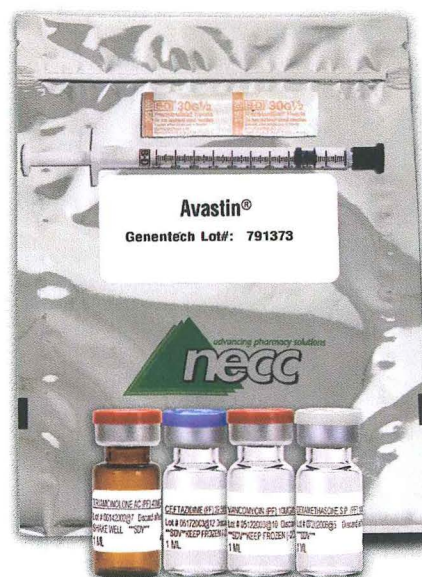
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Attn: Vitreoretinologists

Are you having difficulty obtaining medication in the concentration, volume or dosage form best suited for your patients?

NECC can help by providing compounded medications on a patient-specific basis.

- Dexamethasone Preservative-Free
- Triamcinolone Preservative-Free (40mg/mL)
- Frozen Antibiotics (Unit Dose Vial)
 - Ceftazidime (22.5mg/mL)
 - Vancomycin (10mg/mL)
- Avastin™ (Unit Dose Syringe)



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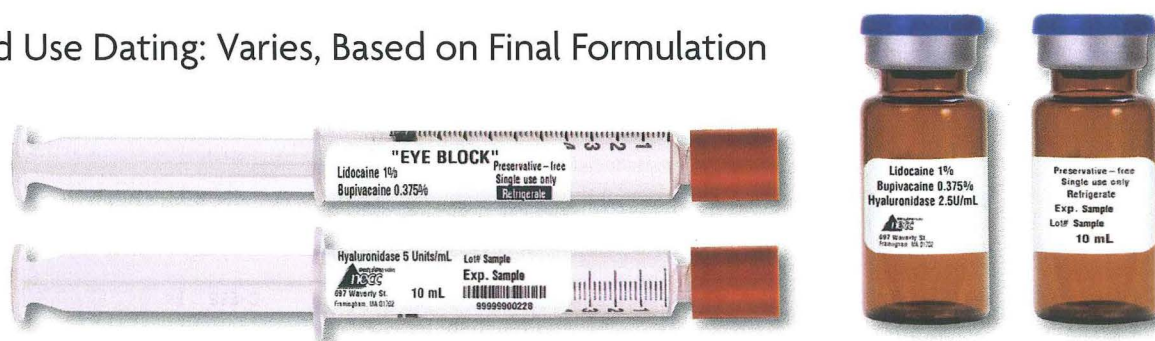
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Retro Bulbar Blocks

- **Lidocaine in Various Concentrations (mg/mL or %)**
- **Bupivacaine in Various Concentrations (mg/mL or %)**
- **Hyaluronidase in Various Concentrations (Units or mL)**
- Available in Various Concentrations (Custom per Facility)
- Provided in a Luer-lock Syringe with a Tamper Evident Cap and Various Vial Sizes
- Beyond Use Dating: Varies, Based on Final Formulation



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